

and increase the bioavailability of oxacarbazepine using a very small particle size of oxacarbazepine. Such color and storage stability of applicants' tablets is unobvious since the smaller a particle, the greater will be the total exposed surface area of a given mass. Thus, the smaller particle size oxacarbazepine would be expected to be less stable due to the larger surface area which is subject to oxidation.


As noted above, Bourquin specifically notes in column 1, lines 18-21, that the unwanted discoloration of the white tablets is caused by the formation of a minor amount ( $<0.05\%$ ) of an oxidation product of oxacarbazepine. The only mention Bourquin makes of particle size is in Example 1 where Bourquin prepares oxacarbazepine tablets by compacting a mixture of oxacarbazepine and excipients to 2-6 mm coarse granules. The size 2-6 mm is one-thousand times larger than  $2\text{ }\mu\text{m}$  to  $12\text{ }\mu\text{m}$ , however, excipients are included with the oxacarbazepine in the tablet core. Thus, Bourquin teaches away from using smaller particle sizes of oxacarbazepine because Bourquin wants to reduce or eliminate oxidation of the oxacarbazepine, and a larger particle size of oxacarbazepine would be expected to be less susceptible to oxidation.

A further unexpected feature of applicants' tablets, as claimed, is that a single hydrophilic coating is applied over the tablet core. In contrast, Bourquin clearly teaches that a double layered coating is necessary to achieve color stability and storage stability for oxacarbazepine tablets. Thus, applicants are able to achieve color stability by using a very small particle size oxacarbazepine and only a single coating on the tablet.

Applicants respectfully request that the rejection of the claims under 35 U.S.C. 103(a) be withdrawn, and that pending Claims 16-20 be passed to allowance.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza  
East Hanover, NJ 07936-1080  
(862) 778-7945

  
John D. Thallemer  
Attorney for Applicant  
Reg. No. 34,940

Date: March 5, 2003